

MAR 26 2002

K014303

510 (K) Summary

Submitter: Jostra AG
Hechinger Straße 38
72145 Hirrlingen
Germany

Contact Person: Kathleen Johnson
Phone: (610) 932-7738
Fax: (610) 932-7366

Date Prepared: December 21, 2001

Device Trade Name: Jostra Retrograde Cardioplegia Cannula

Common/Usual Name: Retrograde Cardioplegia Cannula

Classification Names: Cardiopulmonary Bypass Vascular Cannula
Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, or
Fitting
Catheter Stylet
Piston Syringe

Predicate Device: Medtronic DLP Retrograde Cardioplegia Cannula

Device Description:

The Jostra Retrograde Cardioplegia Cannulas are single, sterile devices for single use only and not to be resterilized by the user. The cannulas are to be used to infuse blood or cardioplegia arrest solution retrograde via the coronary sinus during extracorporeal circulation. The cannulas are made from polyvinyl chloride (PVC) in size 14 Fr. with a variety of balloons, with or without pressure monitoring lines and a choice of stiff or flexible stylets.

Indications for use:

The Jostra Retrograde Cardioplegia Cannulas are designed to be used to infuse blood or cardioplegia arrest solution to the myocardial tissue retrograde via the coronary sinus during cardiopulmonary bypass up to 6 hours or less.

Statement of Technical Characteristics Comparison:

The Jostra Retrograde Cardioplegia Cannulas have the same intended use as the Medtronic DLP Retrograde Cardioplegia Cannulas. Comparative testing has demonstrated that these differences do not affect safety and effectiveness.

Non-Clinical Testing:

Biocompatibility and performance testing was performed to demonstrate substantial equivalency to the predicate device.

Performance testing included:

- Flow-Pressure curves
- Kink Resistance
- Bond Strength
- Leakage Test

Additionally, in-vitro testing was performed to determine the effects on cellular components.

Conclusion:

Performance, and in-vitro testing demonstrate that the Jostra Retrograde Cardioplegia Cannulae are "substantially equivalent" to the predicate devices in intended use, principles of operation, materials, design, and performance.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 26 2002

Ms. Kathy Johnson
Regulatory Affairs, Submission Manager
JOSTRA® AG
c/o JOSTRA-Bentley Corporation
478 Media Road
Oxford, PA 19363

Re: K014303
Trade Name: Jostra Retrograde Cardioplegia Cannula
Regulation Number: 21 CFR 4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing.
Regulatory Class: Class II (two)
Product Code: DWF
Dated: December 21, 2001
Received: December 31, 2001

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality

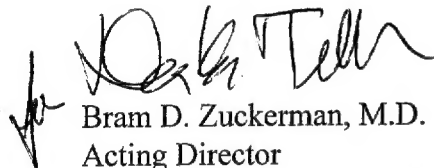
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systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman".

Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
And Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number:


Device Name: Jostra Retrograde Cardioplegia Cannulas

Indications for Use


The Jostra Retrograde Cardioplegia Cannulas are designed for the infusion of blood or cardioplegia arrest solution to the myocardial tissue retrograde via the coronary sinus system during cardiopulmonary bypass up to 6 hours or less.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division of Cardiovascular & Respiratory Devices
510(k) Number K014303

(Optional Format 3-10-98)

Prescription Use 
(Per 21 CFR 801.109)